ORIGINAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and THE STATE OF NEW YORK *ex rel.* PETER OTTAVIO,

Plaintiff,

vs.

RESMED Inc.,

Defendants.

COMPLAINT

CV-17 5734

Index No.

JURY DEMAND

FEUERSTEIN, J.
SHIELDS, M.J.

Plaintiff Peter Ottavio, D.O. ("Ottavio"), by his attorneys, Garfunkel Wild, P.C., alleges for its Complaint against ResMed Inc., that:

PRELIMINARY STATEMENT

1. Relator brings this action on behalf of the United States of America to recover losses from false claims submitted and caused to be submitted to the Medicare program as a result of the sustained fraudulent conduct of defendants ResMed. This action is brought pursuant to the False Claims Act, 31 USC § 3729, *et seq.*, ("FCA"), seeking treble damages, civil penalties, costs and attorneys' fees.

2. From December of 2010 to the present ResMed, a leading manufacturer of Continuous Positive Airway Pressure ("CPAP") therapy equipment, caused the submission and payment of thousands of false claims to the Medicare program for CPAP therapy equipment and testing in violation of Medicare rules and regulations. Put simply, ResMed has implemented a marketing strategy designed to subvert Medicare regulations and enrich ResMed by persuading, encouraging and enabling primary care doctors and other non-sleep specialist physicians to perform and bill for incomplete home sleep tests using ResMed equipment, and to prescribe

expensive ResMed CPAP therapy products for Medicare patients who were purportedly suffering from sleep apnea. In fact, the sleep tests performed by the ResMed equipment that the physicians relied on to bill and to prescribe CPAP therapy were inadequate and incomplete because they were not interpreted by a sleep specialist, as Medicare requires, and the tests were therefore non-reimbursable. Further, and the CPAP therapy prescribed as a result of these tests was not reimbursable because Medicare requires complete testing, including interpretation by a sleep specialist, before it will reimburse patients for CPAP therapy. As a result of this conduct, patients' health has been endangered and ResMed indirectly received millions of Medicare dollars as a result of the false claims ResMed caused to be submitted to the Medicare program for sleep studies and equipment that Medicare would not have paid for, had the program known the true facts about ResMed's scheme, and the falsity of the submitted claims.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the claims under the False Claims Act, 31 U.S.C. 3729, *et seq*.

4. Venue is appropriate in this District pursuant to 31 U.S.C. 3732(a) and 29 U.S.C. 1391(b) and (c), because ResMed does business in this district and a substantial part of the events or omissions giving rise to the claims occurred in this district.

PARTIES

5. Plaintiff/Relator is a Sleep Specialist, and is a Board Certified Diplomate in Pulmonary, Critical Care and Sleep, who brings this action on behalf of the United States of America.

6. Defendant ResMed is a publicly traded corporation, incorporated in the state of Delaware. ResMed is one of the leading Manufacturers of equipment used for Sleep Apnea diagnosis and treatment in the United States.

THE FALSE CLAIMS ACT

7. The FCA provides that any person who, with actual knowledge, or in reckless disregard or deliberate ignorance of the truth, submits or causes to be submitted a false or fraudulent claim to the United States Government for Payment or approval is liable for a civil penalty of up to $21,563 for each claim, plus three times the amount of the damages sustained because of the false claim. 31 U.S.C. § 2729, *et seq*

8. Under 31 U.S.C. § 3730(b), a private individual, known as a relator, may bring a civil action or *qui tam* suit for a violation of the FCA on behalf of the United States.[1] The United States can elect to intervene and assume primary responsibility for the action, but even if it declines to do so, the relator may proceed. *Id.*, §§ 3730(c)(1), 3730(b)(4)(B). Whether the government intervenes or not, the relator may share in any recovery—with the percentage of the relator's award varying depending on whether the Government intervenes or not - plus reasonable expenses, fees and costs. *Id.* §§ 3730(d)(1)–(2);

9. The FCA requires that the complaint in a *qui tam* action be filed under seal without service on any defendant. The complaint remains under seal while the United States conducts an investigation of the allegations in the complaint and determines whether to intervene.

[1] " '*Qui tam*' comes from the phrase '*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,' which translates as 'who pursues this action on our Lord the King's behalf as well as his own.' " *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 n.4 (1st Cir. 2007) (quoting *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 463 n.2, 127 S.Ct. 1397, 167 L.Ed.2d 190 (2007)), overruled on other grounds by *Allison Engine v. United States ex rel. Sanders*, 553 U.S. 662, 128 S.Ct. 2123, 170 L.Ed.2d 1030 (2008).

FACTUAL BACKGROUND

A. The Medicare Program

10. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426a. Medicare is administered by the Centers for Medicare & Medicaid Services ("CMS"), which is part of the Department of Health and Human Services ("HHS").

11. The Medicare program is divided into four parts: Part A, Part B, Part C, and Part D. This case concerns payments made under Medicare Part B. Medicare Part B covers, among other things, payment for physicians' services, services and supplies incident to physicians' services, diagnostic tests, and Durable Medical Equipment (DME) for use in beneficiaries' homes.

12. CMS relies on a network of Medicare Administrative Contractors (each a "MAC") to serve as the primary operational contact between the Medicare program and the health care providers enrolled in the program. A MAC is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) medical claims or Durable Medical Equipment (DME) claims for Medicare Fee-For-Service (FFS) beneficiaries.

13. Individuals enrolled in the Medicare Program may also obtain their Medicare Part A and Part B coverage through Medicare Part C, also known as Medicare Advantage, which is

the Medicare managed care program, from Medicare-approved private health insurance plans, or from Original Medicare, Part A and Part B.

14. CMS makes National Coverage Determinations and rules. A Local Coverage Determination (LCD) is a decision by a MAC whether to cover a particular service on a MAC-wide, basis.

15. All Medicare providers must enroll in the program as providers, and are expected to deal honestly with the Government and with patients.

16. CMS develops guidelines including National Coverage Determinations ("NCDs") for an item or service to be applied on a national basis for all Medicare beneficiaries meeting the criteria for coverage under the Social Security Act. MACs develop Local Coverage Determinations on whether to cover a particular service in accordance with section 1862(a)(1)(A) of the Social Security Act to provide guidance to the public and medical community, including when there is no NCD or when there is a need to further define an NCD.

17. Federal regulations require, as a condition of Medicare payment, that services must have been furnished by a provider or supplier that was, at the time it furnished the services, qualified to have payment made for them. 42 C.F.R. § 424.5(a)(2).

18. To make a claim for services or supplies, the provider or supplier must furnish to the MAC sufficient information to determine whether payment is due and the amount of the payment. 42 C.F.R. § 424.5(a)(6).

19. To obtain Medicare reimbursement for certain outpatient items or services, providers submit claims using forms known as CMS 1500s. Among the information the provider

includes on a CMS 1500 form are certain five-character alphanumeric codes, known as Healthcare Common Procedure Coding System ("HCPCS") codes that identify the services rendered and for which reimbursement is sought.

20. The HCPCS is divided into two principal subsystems, referred to as level I and level II of the HCPCS.

21. Level I of the HCPCS is comprised of CPT (Current Procedural Terminology), a five-digit numeric coding system maintained by the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals.

22. Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.

23. The United States reimburses Medicare providers with payments from the Medicare Trust Fund, through CMS, as supported by American taxpayers. CMS, in turn, contracts with private contractors referred to as "fiscal intermediaries," "carriers," and Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by healthcare providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100.

24. National Government Services, Inc. was the MAC responsible for processing Medicare Part B claims in the State of New York since at least 2010.

25. Noridian Healthcare Solutions, LLC ("Noridian,"), Novitas Solutions, Inc. ("Novitas"), Cahaba Benefit Administrators, LLC, Wisconsin Physician Services Insurance Corp, First Coast Service Options, Inc. ("First Coast"); Palmetto GBA ("Palmetto"), and CGS Administrators, LLC ("CGS") are currently and/or were the MACs responsible for processing Medicare Part B claims during the relevant time period.

26. Durable Medical Equipment MACs are responsible for providing coverage guidance on CPAP devices. NGS, Noridian, CGS, and NHIC, Corp. are currently and/or were the Durable Medical Equipment MACs responsible for providing coverage guidance during the relevant time period.

27. During the relevant time period, Defendants knowingly submitted and caused to be submitted claims to Medicare through NGS, Noridian, NHIC and others, that Defendants knew, or deliberately disregarded or acted in reckless disregard of the knowledge that it was false.

28. The Social Security Act governs Medicare payments for all services. Medicare covers services that it considers "reasonable and necessary," including services used to diagnose or treat a disorder. Social Security Act § 1862(a)(1)(A); 42 U.S.C. § 1395y(a)(1)(A). MACs may specify additional coverage requirements through Local Coverage Determinations ("LCDs"). CMS, Medicare Program Integrity Manual, Pub. No. 100-08, Ch. 13, § 13.1.3.

29. Because it is not feasible for the Medicare program, or its contractors, to review the patient files for the millions of claims for payments it receives from providers, the Medicare program relies upon the providers to comply with the Medicare requirements, and trusts the providers to submit truthful and accurate claims.

30. All Medicare providers must have, in each of their patients' files, the medical documentation to establish that the Medicare items or services for which they have sought Medicare reimbursement are reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1395g(a).

B. Obstructive Sleep Apnea

31. Obstructive Sleep Apnea is defined by the National Institutes of Health as "a common disorder in which you have one or more pauses in breathing or shallow breaths while you sleep." The condition is chronic, and in addition to disrupting sleep, leading to daytime fatigue, sleep apnea can increase the risk of high blood pressure, heart attack, stroke, obesity, and diabetes, and it can increase the risk of, or worsen, arrhythmias, or irregular heartbeats.

32. Obstructive Sleep Apnea is caused by a physical blockage of the airways used to breathe during sleep. For example, the tissue in the back of the throat may collapse during sleep, or, particularly for individuals who sleep on their back, the tongue can fall into a blocking position.

33. Sleep Apnea is difficult to diagnose. Because the plainest symptoms, including snoring and waking up at night, occur only while sleeping, a routine physical will not uncover the condition. There is no blood test or daytime in-office procedure to diagnose sleep apnea.

34. As a result, sleep apnea is typically diagnosed in a sleep lab. Patients who report symptoms consistent with sleep apnea, such as daytime tiredness, snoring, and frequent waking at night, to their primary care physician are referred to sleep specialist. They spend an evening at a sleep lab, sleeping with sensors attached to their scalp, face, chest, limbs, and a pulse oximeter[2] attached to a finger, while trained technicians monitor them throughout the night. A physician

[2] A pulse oximeter is a medical device that indirectly monitors the oxygen saturation of a patient's blood. Frequent and significant changes in oxygen saturation are indicative of sleep apnea.

specialist reviews the results of the test to see whether the patient has sleep apnea and, if so, how severe it is. Based on the test results the sleep specialist will prescribe a course of treatment.

35. Alternatively, sleep apnea can be diagnosed with the use of an in-home sleep monitoring device. In-home sleep apnea diagnostic devices typically require the patient to strap a small mechanical unit to their chest, and the unit connects to tubing that is inserted into the nostrils, as well as to a pulse oximeter that is attached to the patient's finger. The test usually lasts one night.

36. The data recorded on the in-home device is then provided to a physician who is a sleep specialist for interpretation and diagnosis.

37. As with an in-office sleep study, if the test results indicate that the patient is suffering from some degree of sleep apnea, the physician sleep specialist will consider a range of options for treatment.

38. These options include lifestyle changes (exercise, weight loss, improved sleep habits), the use of oral appliances to address the problem, CPAP therapy, surgery, and possibly additional alternative sleep therapies.

39. What therapy is appropriate depends on a number of factors, but one of the primary considerations is the degree of sleep apnea. As is explained in more detail below, sleep apnea intensity is measured by the number of incidents of breathing cessation for 10 seconds or more per hour, as reflected in the sleep study results. A number over 5 but below 15 is considered mild sleep apnea. 15 to 30 is considered moderate sleep apnea, and over 30 incidents per hour is considered severe.

C. Central Sleep Apnea

40. Central sleep apnea is different from obstructive sleep apnea. Central sleep apnea is not caused by a blockage of the airway. Central sleep apnea is caused by an abnormality in the

brain that results in the failure to send the proper signals to the muscles that control breathing. Estimates of Central Sleep Apnea frequency from the American Sleep Apnea Association suggest that it may account for 20% of Sleep Apneas.

41. Central Sleep Apnea treatment is far more complex than treatment of Obstructive Sleep Apnea. Depending on the cause, Central Positive Airway Pressure (CPAP) may be an indicated treatment for Central Sleep Apnea. However, in certain situations, not only are other therapies, such as Bi-level Positive Air Pressure or Adaptive Servo-Ventilation are appropriate treatments. In fact, CPAP therapy can actually be dangerous for some sufferers of Central Sleep Apnea.

D. CPAP Therapy

42. CPAP therapy is prescribed for patients suffering from significant Obstructive Sleep Apnea, at a level that is unlikely to respond to lifestyle changes or oral appliances. The therapy utilizes CPAP machines, which typically consist of a mechanical box, tubing, and a mask worn over the patient's nose and mouth while the patient sleeps. A CPAP system is specifically designed to deliver a constant flow of mild air pressure to the patient's lungs to keep the airways continuously open, and thereby eliminate the pauses or shallow breathing that characterize sleep apnea.

43. Effective CPAP therapy requires supervision by a physician who is a sleep specialist to properly set and adjust the machine to ensure that the rate of air flow and pressure is commensurate with the degree of the patient's sleep apnea.

44. The price for a CPAP machine ranges from about $500 to $3000, with an estimated average price around $850.

E. The Medicare Program's Reimbursement Policies Regarding Sleep Apnea

45. Medicare will reimburse health care providers and/or patients for sleep apnea diagnosis and treatment in certain circumstances, as explained below.

1. Testing and Analysis

46. If a patient reports symptoms indicating they may have sleep apnea, Medicare will reimburse the cost of sleep apnea testing. This includes the cost of an overnight sleep study at a sleep center that is certified by Medicare, and the analysis of the results by a sleep specialist physician. *See* CMS, Decision Memo for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAD-000405N) (March 3, 2009) ("NCD Sleep Testing for OSA").

47. Diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) "who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a).

48. To provide Home Sleep Test ("HST") services, "The sleep test must have been … ordered by the beneficiary's treating physician and furnished under appropriate physician supervision." *See* CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chap. 1, Part 4 (Rev. 189, 02-05-16, (Rev. 190, 02-05-16), § 240.4 "Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (Rev. 96, Issued: 10-15-08, Effective: 03-13-08, Implementation: 08-04-08) ("NCD 240.4").

49. Diagnostic tests payable under the physician fee schedule that are furnished without the required level of supervision by a physician are not reasonable and necessary. 42 C.F.R. §410.32(b).

50. As an alternative to sleep testing in a certified sleep center, and after initially rejecting the use of in-home testing as not reasonable and necessary, since 2008 Medicare will reimburse the cost of FDA approved in-home sleep apnea testing HST using portable monitors, and analysis of the results. (NCD 240.4)

51. Pursuant to 42 C.F.R. § 424.57(a) "Sleep test means an attended or unattended diagnostic test for a sleep disorder whether performed in or out of a sleep laboratory. The 'provider of the sleep test' is the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test."

52. Medicare, in a decision memo regarding sleep tests, explained "a sleep test should be interpreted by a skilled and knowledgeable physician. We also agree that a physician who is board certified or board eligible in sleep medicine is likely to have those characteristics across the spectrum of sleep disorders diagnosis and management." In this decision, Medicare declined to opine more specifically on the required certification of the interpreting physician, saying "Comments about specific physician specialties are outside the scope of this NCA [National Coverage Analysis]". See CMS, Decision Memo for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAD-000405N) (March 3, 2009).

53. However, pursuant to multiple LCDs, the MACs only permit sleep specialist physicians to conduct and be reimbursed for test result evaluations and the sleep specialist must also review and interpret the results. *See, e.g.,* NGS, LCD for Polysomnography and Sleep Studies (L26428), requiring "For services to be reported as sleep studies or polysomnography, the patient must sleep six or more hours, with physician review, interpretation and report of the study." and further stating, "Sleep testing performed using an unattended portable monitor (home sleep testing (HST)) for the diagnosis of obstructive sleep apnea must adhere to the guidelines

specified in 'Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients' " (Journal of Clinical Sleep Medicine, Vol. 3, No. 7, 2007) (the Clinical Guidelines, in turn, specify "A board certified sleep specialist, or an individual who fulfills the eligibility criteria for the sleep medicine certification examination, must review the raw data from PM using scoring criteria consistent with current published AASM standards.);[3] *See also*, Noridian, LCD L34040, Polysomnography and Other Sleep Studies (October 2015); Noridian, LCD L32416 Polysomnography and Sleep Studies for Testing Sleep and Respiratory Disorders (internal citations omitted) ("the sleep test (Type 1 - IV, Other) must be interpreted by a physician who holds either: a) Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or b) Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or c) Completed residency or fellowship training by a program approved by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or d) Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations - JCAHO)."); Novitas, LCD L32711 - Outpatient Sleep Studies (Effective 10/29/2012) "All sleep studies (in facility or home based) are to be supervised and with an over read by an ABSM Board Certified Sleep Medicine

[3] *See also*, NGS, ARTICLE FOR POLYSOMNOGRAPHY AND SLEEP STUDIES – MEDICAL POLICY ARTICLE, (June 10, 2016) (A53019) ("HST scoring must be performed by an individual certified by the Board of Registered Polysomnographic Technologists as a Registered Polysomnographic Technologist (RPSGT), or equivalent, or by a polysomnographic technician under the supervision of a RPSGT, or by a Registered Respiratory Therapist-Sleep Disorder Specialist (RRT-SDS) or a Certified Respiratory Therapist-Sleep Disorder Specialist (CRT-SDS), or equivalent.").

physician or ABSM Board Certified psychologist with a PhD by January 1, 2012." ; Novitas, LCD L32711 - Outpatient Sleep Studies (Effective 10/29/2012 ("The accuracy of diagnostic sleep studies depends on the knowledge, skill, and experience of the technologist and interpreter and does not matter if Type I, II, III, or IV or where the test is performed. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit.").

54. In summary, in order for diagnostic testing to be reasonable and necessary under §1862(a)(1)(A) of the Social Security Act and for coverage for a Home Sleep Test (HST) (Type II, III, or IV), pursuant to LCD's issued by the Medicare Administrative Contractors and the published policy of the Durable Medical Equipment Administrative Contractors, unattended home sleep tests used must be interpreted by a physician who:

- Holds either current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or, current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or,
- Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or, is
- Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations - JCAHO).

See, e.g., Noridian, Dear Physician Letter (December 18, 2008), Positive Airway Pressure (PAP) Devices – Important Information for the Ordering Physician; CGS, Positive Airway Pressure (PAP) Devices – Important Information for the Ordering Physician (Originally Pub'd December 2008, updated Nov. 2016). CGS & Noridian, Local Coverage Determination (LCD) No. L33718 - Positive Airway Pressure System (PAP) Devices for the Treatment of Obstructive Sleep Apnea. (updated 05/03/2017 with effective dates 01/01/2017).

55. The Office of Inspector General ("OIG") has identified claims for the technical component of sleep study services that have no corresponding professional component claim as a

questionable billing practice ripe for fraud. Specifically, it noted that where there regularly is no corresponding claim for the professional component submitted by any provider for sleep studies, providers may be routinely billing for services not rendered. *See* Department of Health and Human Services, Office of Inspector General, Questionable Billing for Polysomnography Services (OEI-05-12-00340) (October 2013), p. 9.

56. Providers bill Medicare for Home Sleep Testing using codes G0398, G0399 and G0400. The Place of Service is generally listed as the patient's home (POS 12) and sometimes listed as an independent diagnostic testing facility (POS 15) if performed in a mobile IDTF. Home sleep testing services consist of two components: the administration of the test (the technical component) and the physician's interpretation of the test (the professional component). The Professional component is billed as 26, and the technical component is billed as TC. *See* MLN Matters No. MM6094, Related Change Request 6094 (Release Date: June 19, 2008 Effective Date: July 1, 2008), p. 4; *see also* CMS Pub 100-03 Medicare National Coverage Determinations, Transmittal 86, July 3, 2008, Change Request 6048, Section, I, B.

57. Where the technical and professional component of the service are provided by different individuals or entities, Medicare permits the splitting of payment for the service to be billed for separately, as noted, by using a modifier "26" added to the HCPCS code to indicate the professional component of the charge, and the modifier "TC" to indicate the technical component of the service. Where the technical and professional component of the service is provided by a single individual or entity, the service is billed as a global charge, equal to the combined professional and technical charges.

58. G03998 is the appropriate coding for Home Sleep Test (HST) with a type II portable monitor, that is unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation

59. G0399 is the appropriate coding for HST with type III portable monitor, unattended, using a device with a minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation.

60. G0400 is the appropriate coding for HST with type IV portable monitor, unattended; minimum of 3 channels

3. Medicare Policy Regarding Sleep Apnea Test Results And Requirements For CPAP Coverage

61. Sleep apnea is measured in two ways. One is the apnea hypopnea index ("AHI"), a number that is equal to the average number of episodes of apnea (breathing cessation for at least 10 seconds) and hypopnea per hour. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.[4]

62. The second sleep apnea measurement is the respiratory disturbance index ("RDI"), which is equal to the average number of respiratory disturbances per hour.

63. The Durable Medical Equipment MACs will only authorize reimbursement for CPAP therapy if the results of either a sleep lab test or an in-home test are interpreted by a physician who is a sleep specialist, and if that specialist certifies that the patient's test results meet certain Medicare diagnostic requirements for CPAP therapy.

[4] The minimum of 4% oxygen desaturation is a Medicare standard. Other payors may require only 3%, which is the standard recommended by the American Academy of Sleep Medicine.

64. In order to be eligible to receive payment for a Medicare-covered item, a durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") supplier must submit a completed application to CMS to furnish Medicare-covered items including required enrollment forms. 42 C.F.R. § 424.57(b)(1).

65. Medicare will cover an initial 12-week period of CPAP therapy in adult patients with sleep apnea only if either of the following criteria using the AHI or RDI are met:

- AHI or RDI greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

See NCD 240.4.

66. As noted, Medicare requires that the necessary AHI or RDI findings be made by a sleep specialist. *See* Noridian, Dear Physician Letter Positive Airway Pressure (PAP) Devices – Important Information for the Ordering Physician (December 18, 2008); CGS, Positive Airway Pressure (PAP) Devices – Important Information for the Ordering Physician (Originally Pub'd December 2008, updated Nov. 2016).

67. After the initial 12 week period of CPAP therapy, Medicare will cover continued therapy if a physician sleep specialist certifies that the patient is at least 70% compliant with CPAP therapy instructions (*i.e.*, uses a CPAP at least 7 out of 10 days).

F. Defendant ResMed And In Home Sleep Testing

68. Defendant ResMed is a leading manufacturer of both CPAP machines and the equipment that accompanies these machines, including masks, filters and other accessories.

69. ResMed also manufactures home sleep apnea diagnostic products, including "ApneaLink," which ResMed touts as "simple, fast and easy to use," on their website.

1. "Automatic Scoring" Of In Home Sleep Tests

70. In addition to producing raw data for analysis by a sleep specialist, ResMed's ApneaLink home testing device offers an option known as "automatic scoring." In this mode the ApneaLink machine connects to ResMed software and performs a computer generated analysis of the data, resulting in purported AHI and RDI levels. It is this "feature" that is the centerpiece of Resmed's scheme.

71. ResMed claims that the ApneaLink provides "accurate and useful results."

72. In addition, ResMed markets the ApneaLink as providing "reliable automatic analysis," and ResMed advises health care professionals that "validated results meet AASM and CMS definitions for hypopnea snoring guidelines."[5] This statement is palpably false.

73. The ResMed website, in a section directed at "Healthcare Professionals," explains in home testing by advising that "[t]here are two types of setups for a home sleep study." ResMed first discusses an at home study supervised by a sleep specialist, and then informs the Healthcare Professional that:

> A simpler home setup can be performed using ResMed's ApneaLink™ Air, a compact, lightweight and easy-to-use home sleep testing device. The ApneaLink Air is capable of recording up to five channels of information, including respiratory effort, pulse, oxygen saturation, nasal flow and snoring.[6]

74. The ResMed 2016 Annual Report, filed with the Securities and Exchange Commission, contains the following claim about the ApneaLink:

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[5] From the website http://www.resmed.com/us/en/healthcare-professional/products/diagnostics/apnealink-air.html : "**Accuracy.** You're provided with a clear diagnosis and effective reports that meet AASM and CMS definitions for hypopnea scoring guidelines." Last visited August 8, 2017.

[6] http://www.resmed.com/us/en/healthcare-professional/diagnosis-and-treatment/sleep-disordered-breathing/screening-and-diagnosis/all-about-sleep-studies.html Last visited August 8, 2017.

> A portable diagnostic device which measures oximetry, respiratory effort, pulse, nasal flow and snoring. Works with EasyCare Online [ResMed Software] to provide comprehensive diagnostic solution to clinicians. (emphasis added).

75. In fact, studies demonstrate that ApneaLink automatic scoring results are unreliable, particularly in the lower, or "borderline" ranges.

76. Further, in Relator's experience, ApneaLink often fails to diagnose severe levels of sleep apnea, instead reporting that such patients are suffering from mild sleep apnea or no sleep apnea at all. This is extremely dangerous to the patients, since the less serious (as well as the incorrectly negative) diagnoses are likely to lead the patient to believe that treatment is not necessary.

77. More importantly, ResMed's marketing claims fail to advise physicians to whom they market the ApneaLink that a valid sleep test requires an analysis of the data by a sleep specialist, and that reliance on the "autoscoring" feature is not permitted. Instead, ResMed's marketing encourages primary care physicians to use the ApneaLink for an at home test, and then prescribe therapy, specifically, a ResMed CPAP machine, if the autoscored results reflect a diagnosis of sleep apnea.

78. The Medicare program recognizes that diagnosis of sleep apnea is a difficult and complex medical task, which requires training and expertise. As a result, the MACs require that before Medicare will pay for CPAP therapy, there must be a diagnosis of obstructive sleep apnea by a certified sleep specialist, and the specialist must certify that the level of apnea meets the Medicare requirements. As described in more detail above (see e.g., ¶ 56), Medicare will not reimburse CPAP therapy that is prescribed on the basis of a non-specialist's evaluation of test

results, and will not reimburse CPAP therapy that is prescribed on the basis of an automatic score from ApneaLink or any similar product.

79. Thus, while a primary care physician or cardiologist is certainly capable of administering an at home sleep test (the "technical component"), before Medicare will reimburse for the testing or reimburse the patient for CPAP therapy, the results must be reviewed and interpreted by physician sleep specialist, and CPAP therapy must be prescribed by a sleep specialist (the "professional component').

F. ResMed's Fraudulent Scheme

80. ResMed's fraudulent marketing scheme was designed to evade Medicare's requirement that a certified sleep specialist be involved in the diagnostic process before Medicare will reimburse the cost of CPAP testing or therapy. In order to maximize the number of ResMed CPAP machines that are prescribed for Medicare patients and paid for by Medicare, ResMed has engaged in a marketing campaign that systematically enables and encourages non-sleep specialist physicians to prescribe CPAP therapy for patients who have never seen a sleep specialist, and whose home test results have not been reviewed by a sleep specialist.

81. ResMed representatives market the ApneaLink to primary care doctors and cardiologists who are not certified sleep specialists. ResMed representatives meet with primary care doctors and cardiologists and stress to these physicians that an ApneaLink machine can produce substantial revenue for their practice. ResMed's marketing also makes this point. ResMed advises that a doctor can purchase an ApneaLink device, prescribe an at-home sleep test for patients and be reimbursed for the "technical component" of at home sleep testing. ResMed does not inform the physicians that the resulting data must be evaluated by a sleep specialist.

82. In fact, a ResMed sales representative admitted to the Relator that she often just gives the ApneaLink devices to physicians, at no charge, despite the fact that they can retail for over $4,000, to induce them to start using it.

83. However, ResMed representatives fail to advise doctors that the test results, including the automatic results generated by the ApneaLink, are insufficient under Medicare rules to support a prescription for CPAP therapy, and that an interpretation of the data by a sleep specialist to complete the test is required.

84. Instead, as described above, ResMed's marketing suggests that ResMed's "automatic scoring" feature provides "reliable results" which meet the Medicare requirements.

85. The ApneaLink was designed to connect to the ResMed website's "ApneaLink PC Software" platform to enable a physician to obtain the "automatic scoring" result. Once the patient has used the ApneaLink for an overnight sleep test, and returns the device, the physician logs in to ResMed's website and transfers the data.

86. The ResMed software offers the physician the option to obtain the automatic score. If the physician selects this option, the software produces a report with a "result": an AHI number. When the physician prints the report out, either for his records or to share with the patient, the ResMed software automatically prints out both the report and a ResMed Order Form for a ResMed CPAP machine.

87. Physicians routinely rely on what ResMed tells them is the "reliable" autoscoring feature, both because it is quick and easy, and because absent substantial training, Physicians are completely unable to understand the data retrieved by the ApneaLink.

88. Attached hereto as Exhibit 1 is an actual printout of a ResMed "automatically scored" report for an actual patient. The report states that the patient had an AHI of 5.9 (rounded up to 6) and suffered from mild sleep apnea. (An AHI over 5 indicates Sleep Apnea).

89. Attached hereto as Exhibit 2 is the next page that printed out. It is titled "Prescription for Therapy," but it is actually little more than an order form for a ResMed CPAP machine and related supplies.

90. The ResMed Order Form offers the doctor three diagnosis choices: Obstructive Sleep Apnea, Primary Central Sleep Apnea, and Cheyne-Stokes Breathing Pattern (a type of Central Sleep Apnea). More importantly, however, the ResMed form offers the doctor one treatment option: a ResMed "Autoset" CPAP machine. In fact, the form contains a note that says "Do not substitute."

91. The form also contains a line for the physician's signature beneath the legend:

> Statement of Medical Necessity
>
> The above patient has undergone diagnostic evaluation. This evaluation has confirmed a positive diagnosis of sleep apnea. Positive airway pressure therapy is medically necessary and provides effective treatment of this disorder.

92. It was the goal of ResMed's marketing scheme that the doctor seeing this printout, unaware that further analysis was required before Medicare will cover the technical component of the test, or reimburse CPAP therapy for the patient, would rely on the autoscore feature as providing a "positive diagnosis" of sleep apnea. ResMed's scheme would be complete once the doctor fills out the order form and gives it to the patient with a recommendation to purchase and utilize ResMed's CPAP therapy.

G. ResMed's On Line ApneaLink Tutorial

93. ResMed furthered its scheme by offering providers a misleading and incomplete on-line "tutorial" regarding the use of ApneaLink and "ApneaLink PC Software." Located at ResMed's website, the tutorial is plainly directed at primary care and non-sleep specialist physicians. It includes an explanation of what sleep apnea is, how widespread it is, and offers advice about how to teach your patient to use the ApneaLink device at home.

94. After instructing providers about how to download the data onto a PC using the ApneaLink software the tutorial instructs providers about how to "interpret" the results.

95. In the section of the tutorial labeled "Report Interpretation" ResMed begins "Let's now see how to interpret the report." The "report" is the auto-scored software report produced automatically by the ResMed software. As noted above, an auto-scored report is not sufficient to justify a diagnosis of Sleep Apnea under any circumstances.

96. The video tutorial displays a sample copy of an autoscored report and describes various aspects of it, and mentions that the report omits "periods when the signal was too small for analysis." This is one of the reasons autoscored reports are not adequate. While the ApneaLink machine is unable to analyze such periods, a trained specialist can extract valuable information from then when reviewing the raw data.

97. ResMed "recommends" a duration of four hours minimum. As noted above, at ¶ 53, Medicare generally requires a duration of six hours.

98. After describing the sections of the report that reflects AHI as indicating "Apnea Hypopnea Index per evaluation hour," ResMed cautions doctors that "the patient should be referred for a diagnostic test when the AHI is above 10." Of course, this recommendation to refer the patient for a diagnostic test is likely to make little sense to the doctors, since they are

under the impression, having been told so by ResMed, that the autoscored ApneaLink test is a diagnostic test.

99. The tutorial also includes about 30 seconds of advice about actually manually reviewing the ApneaLink data, something Medicare regulations clearly state can only be done by a sleep specialist, and something that obviously cannot be learned during a 30 second tutorial segment. *See* ¶ ¶ 53-54, above.

100. Thus, even if a physician logs into the ResMed website seeking help determining what he should do after his patient completes the test, ResMed assiduously avoids advising the physician what the actual necessary next step is – that the data must be reviewed by a sleep specialist before it can be billed and before CPAP therapy can be prescribed.

101. Instead, as noted, when the physician prints out the autoscored report, a form for ordering a ResMed CPAP device, as described above and attached hereto, prints out for them.

102. ResMed's scheme worked. Doctors who use ApneaLink frequently rely on the automatic scoring function and order CPAP therapy for patients whose automatic scores reflect a diagnosis of sleep apnea. Relator has not only personally observed this phenomenon, but has discussed its prevalence with other sleep specialists. In fact, as described in more detail below, relator has described this problem directly to the CEO of ResMed, as well as various other senior ResMed personnell.

False Claims

103. Physicians, relying on false and fraudulent representations from ResMed, ResMed's false and fraudulent marketing claims, and ResMed's false and fraudulent public statements, submitted claims to Medicare for sleep testing done on Medicare patients with the ApneaLink, when the test was autoscored and was never completed by having a sleep specialist

evaluate the results. These claims were not reimbursable, but ResMed benefitted from their submission because the invalid autoscored test results frequently led to orders for ResMed CPAP equipment, and because Medicare reimbursement for the testing gave the physicians incentive to use the ApneaLink. Physicians' use of ApneaLink generated income for ResMed through physician purchases of the ApneaLink, and through patient purchases of ResMed CPAP equipment, which patient purchases were often reimbursed by Medicare.

104. DME providers, relying on the false and fraudulent representations contained in the documents ResMed decieved doctors into creating, submitted false claims to Medicare for CPAP equipment. In order to obtain CPAP equipment and begin CPAP therapy the patient has to place an order with a Durable Medical Equipment (DME) provider. The patient contacts a provider, presents the order form, which should be signed by a doctor, and the DME provider orders the equipment from ResMed. Once the provider furnishes the CPAP equipment to the patient the provider submits a claim to Medicare for reimbursement. This claim is false because, as ResMed intended, it is based on ApneaLink automatic scoring of an at home sleep test, but it impliedly certifies that the patient has been diagnosed as suffering from sleep apnea by a sleep specialist. ResMed benefits from inducing the DME provider to submit these false claims to Medicare because the DME provider pays ResMed for the CPAP equipment using funds it has received from the Medicare program

Materiality

105. The falsehoods contained in the claims ResMed caused to be submitted were material. Medicare regulations do not permit Medicaid to pay for, and Medicare will not pay for: (1) sleep testing; or (2) CPAP therapy, unless a sleep specialist has reviewed the test results and diagnosed the patient as suffering from sleep apnea. ResMed caused thousands of claims to be

submitted to Medicare and paid, for CPAP tests and therapy, despite the fact that the patients' test results were never reviewed by a sleep specialist.

106. In addition, Medicare does not pay for incomplete sleep studies. ResMed caused providers to submit thousands of claims for the technical component of sleep studies when the study was never completed, because it was never analyzed by a sleep specialist, but was only autoscored by the ApneaLink program. Medicare would not have paid these claims if it had known that the test data had never been reviewed by a sleep specialist.

ResMed's Scienter

107. ResMed was well aware that the scheme it designed worked, and that physicians using ApneaLink routinely prescribed ResMed CPAP therapy devices based solely on an automatically scored ApneaLink tests and routinely billed Medicare for the technical component of ApneaLink tests that were never completed.

108. As noted above, as part of its ApneaLink marketing program ResMed maintains a website with software that performs the automatic scoring of Home Sleep Tests. In addition, that website hosts a database of all patients whose ApneaLink results are entered into ResMed's on-line software. The database reflects a patient's sleep apnea score, whether the score is based on automatic scoring or independent analysis by a sleep specialist, and whether the patient has purchased a ResMed CPAP machine.

109. ResMed's system reflects that thousands of patients have been prescribed CPAP therapy systems based on automatic test results that have never been interpreted by a sleep specialist. In fact, if any doctor, not necessarily a sleep specialist, opens the data and looks at it, even for a few seconds, ResMed's software will now mark that test "manually scored." Thus, with respect to the tests on their website marked automatically scored, Resmed knows that no

doctor has ever even looked at the data. Yet ResMed's website shows that thousands of these patients have been prescribed CPAP therapy with ResMed machines.

110. Relator brought this issue to the attention of the CEO of ResMed, and the CEO responded that he was aware of what was happening, but that it was not ResMed's problem – it was the primary care doctors who were not following the Medicare rules. Relator had a similar conversation with the Chief Compliance Officer at ResMed.

111. Relator has also had conversations with the CEO of ResMed, in which the CEO explained to him that ResMed's goal is to take sleep specialists out of the process of starting CPAP therapy. ResMed's plan, as explained to Relator, is that primary care doctors and cardiologists would prescribe CPAP treatment, based on a home sleep test, and, once the patient is using a ResMed CPAP, they will be referred to a sleep specialist to monitor the ongoing treatment.

112. The reason ResMed wants the primary care doctors or cardiologists to prescribe the CPAP is to make sure they prescribe a ResMed machine. ResMed is not the only CPAP manufacturer. Respironics, Fisher and Paykel, DeVilbis, Aeiomed, and others compete for CPAP business. Sleep specialists are well aware of the different CPAP companies, and the differences in the products, and while many recommend ResMed CPAP, many do not. Primary care doctors and cardiologists who ResMed convinces to use the ApneaLink, on the other hand, know little or nothing about other CPAP options beyond what they learn from ResMed's marketing. And when the ResMed CPAP order form prints out based on an autoscored ApneaLink test, these doctors are not likely to look into whether there are other manufacturers to consider.

113. As a result, ResMed's marketing campaign is designed to ensure that patients who are diagnosed with the ApneaLink autoscoring feature, and prescribed CPAP by a primary care doctor or cardiologist based on the autoscore, never consider a CPAP provider other than ResMed. This is why ResMed's software is programmed to automatically print an order form for a ResMed CPAP, and why the form states "no substitutions."

114. Accordingly, ResMed had actual knowledge, or acted with reckless disregard of the fact that ResMed's ApneaLink and automatic scoring system were causing thousands of false claims for reimbursement to be submitted.

Health Risks to Patients

115. ResMed's scheme has numerous deleterious effects, in addition to violating Medicare regulations and defrauding the Medicare program.

116. For example, ApneaLink tests tend to underestimate the severity of a patient's sleep apnea. Relator has repeatedly treated patients who underwent ApneaLink testing with results of mild or no sleep apnea, but who actually suffered high moderate to severe Sleep Apnea, as reflected by the more comprehensive testing done in a sleep lab. In fact, Relator has observed significant under-reporting of the Apnea level in approximately 90 percent of the ApneaLink cases he has reviewed. The remaining cases showed an Apnea level more or less corresponding with the sleep lab results. Relator has never seen an ApneaLink autoscore that overestimates the patient's Sleep Apnea when compared to lab test results.

117. This appears to be consistent with ResMed's goal, since if the ApneaLink test result reflects severe apnea, a non-sleep specialist physician is more likely to refer the patient to a sleep specialist, who may then prescribe a device from a different manufacturer. However, if the ApneaLink reflects only mild or moderate sleep apnea, a non-sleep specialist is far more

likely to simply fill out the ResMed CPAP order form that accompanies the ApneaLink autoscore results.

118. One of the technical reasons ApneaLink often underestimates the severity of a patient's sleep apnea is, as discussed above at ¶ 95, that ApneaLink frequently reports that much, if not most of the data is "unreadable." As a result of limited data, the autoscoring system is unable to accurately gauge the severity of the apnea.

119. However, a sleep specialist, trained in evaluating sleep test results, will be often be able to interpret this "unreadable data" and can correct for the shortcoming in the home sleep test, or, if that is not possible, require a re-test. A primary care physician or a cardiologist do not have the training to do this, and will not do this.

120. A significant portion of the "unreadable" data for ResMed sleep tests may be due to severe apnea episodes. ApneaLink appears to be unable to read these episodes, and as a result it excludes them from the autoscoring analysis. The result is consistent underdiagnosis of the severity of the patient's sleep apnea.

121. Relator has personally observed cases where patients suffering severe sleep apnea were egregiously underdiagnosed by an autoscored ApneaLink report.

122. For example, attached as Exhibit 3 is a ApneaLink auto-scored report for patient X. ApneaLink's auto-scored result reflects an AHI Index of 5, borderline sleep apnea. However, actual in-lab testing showed the patient's AHI Index to be 39, indicating severe sleep apnea.

123. As noted, one of the ApneaLink's shortcomings is that it misses periods of severe apnea, treating the data as unreadable.

124. ApneaLink's under-reporting helps ResMed sell more CPAP machines, but it endangers the patient. ResMed acted knowingly or with reckless disregard of the fact that the use of automated scoring underestimated the severity of the sleep apnea.

125. Aside from the risk that patients will ignore what they incorrectly think is mild sleep apnea, the ResMed scheme endanger patients in another way. CPAP is a single continuous airway pressure delivery system. Medicare beneficiaries with severe sleep apnea such as central sleep apnea generally require use of other devices such as a bi-level positive airway pressure system that delivers two different levels of pressurized air: one for inhalation and the other for exhalation. Under ResMed's scheme to sell more CPAP machines, not only would such a patient risk not receiving appropriate treatment, because their autoscored ApneaLink result did not pick up the severity of their condition, but the continuous positive airway pressure on the airway of a patient with central sleep apnea has the potential to make breathing harder and thus can be life-threatening to such a patient.

126. The Medicare administrative contractors, acting on behalf of the Medicare program, have made a reasonable patient-focused decision to require that a sleep specialist be involved in any diagnosis of sleep apnea and the decision to begin CPAP therapy. ResMed has come up with a way to subvert that decision, so that ResMed will sell more CPAP machines. ResMed caused claims to be falsely submitted to Medicare, and as a result ResMed caused the Medicare program to lose millions of dollars in order to enrich ResMed.

FIRST CLAIM

Violations of the Federal False Claims Act

(31 U.S.C. § 3729 (a)(1)(A)) Presenting False Claims for Payment

127. Plaintiffs incorporate by reference the paragraphs above as if fully set forth herein.

128. Relator, on behalf of the United States, seeks relief against Defendants under Section 3729(a)(1)(A) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

129. As set forth above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in connection with the submission to the Medicare Program of requests for reimbursement for CPAP Machines and for Sleep Apnea Testing.

130. Medicare paid the claims because of Defendants' fraudulent conduct.

131. Medicare would not have paid the claims had they known the true facts and circumstances surrounding the claims.

132. By reason of Defendants' fraudulent conduct, the United States has been damaged in a substantial amount to be determined at trial.

SECOND CLAIM

Violations of the Federal False Claims Act

(31 U.S.C. § 3729 (a)(1)(B)) False Records or Statements

133. Plaintiffs incorporate by reference the paragraphs above as if fully set forth herein.

134. Relator, on behalf of the United States, seeks relief against Defendants under Section 3729(a)(1)(B) of the False Claims Act.

135. As set forth above, Defendants knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim, in connection with the submission to the Medicare Program of requests for reimbursement for CPAP Machines and for Sleep Apnea Testing.

136. Medicare paid the claims because of Defendants' fraudulent conduct.

137. Medicare would not have paid the claims had they known the true facts and circumstances surrounding the claims.

138. By reason of Defendants' fraudulent conduct, the United States has been damaged in a substantial amount to be determined at trial.

Dated: Great Neck, New York
September 28, 2017

GARFUNKEL WILD, P.C.
Attorneys for Plaintiff/Relator

By: _____

John G. Martin
Stacey P. Klein

111 Great Neck Road
Great Neck, New York 11021
(516) 393-2200

1

ResMed

ApneaLink - Report of 6/3/2016 10:20 AM

Treating physician

Referral to

Patient data

First name:	[redacted]	Patient ID:	
Last Name:	[redacted]	DOB:	[redacted]
Street:		Height:	0 ft 0 in
City, ST, Zip:		Weight:	0.00 lbs
Phone:		BMI:	kg/m²

Recording

Date:	6/3/2016
Start:	1:17 AM
End:	6:22 AM
Duration:	5 h 4 min

Evaluation

Start:	1:27 AM
End:	6:26 AM
Duration:	2 h 13 min

AHI*

Result (6)

*See Clinical Guide for abbreviations and detailed threshold parameters

Analysis (Flow evaluation period: 2 h 13 min / SpO2 evaluation period: 3 h 0 min)

Indices		Normal	Result	
AHI*:	[illegible]	< 5 / h	Average breaths per minute [bpm]:	12.60
RI*:	8.7	< 5	Breaths:	1697
Apnea index:	0.8	< 5 / h	Apneas:	2
UAI:	0		Unclassified apneas:	0 (0%)
OAI:	0.5		Obstructive apneas:	1 (50%)
CAI:	0.5		Central apneas:	1 (50%)
MAI:	0		Mixed apneas:	0 (0%)
Hypopnea index:	5	< 5 / h	Hypopneas:	11
% Flow lim. Br. without Sn (FL):	13	< Approx. 60	Flow lim. Br. without Sn (FL):	205
% Flow lim. Br. with Sn (FS):	24	< Approx. 40	Flow lim. Br. with Sn (FS):	376
			Snoring events:	1583
ODI Oxygen Desaturation index*:	7.3	< 5 / h	No. of desaturations:	22
Average saturation:	92	94% - 98%	Saturation <= 90% :	28 min (16%)
Lowest desaturation:	89	-	Saturation <= 85% :	11 min (6%)
Lowest saturation:	81	90% - 98%	Saturation <= 80% :	0 min (0%)
Baseline Saturation:	93	%	Saturation <= 88% :	12 min (7%)
			Saturation <= 86% :	11 min (6%)
Minimum pulse:	45	> 40 bpm		
Maximum pulse:	237	< 90 bpm		
Average pulse:	91	bpm		
Proportion of probable CS epochs:	0	0%		

Analysis status: Analyzed automatically (Hypopneas based on flow only)

Analysis parameters used (Default)

Apnea (20%; 10s; 80s; 1.0s; 20%; 50%; 8%); Hypopnea (50%; 10s; 100s; 1.0s); Snoring (6.0%; 0.3s; 3.5s; 0.5s); Desaturation (4.0%; 0.8s [0.60])

Comments

2

Ordering Provider	Nick Patel, DO	Performing facility	
Reported Date		Accession ID	
Performed Date	05/03/2016 00:00		

ResMed

Prescription for Therapy

Date: 5/3/2016

Patient Name: [redacted] Date of Birth: [redacted] Phone #: _____
Address: _____ City, State: _____ Zip: _____

Prescribing Physician: _____ License #: _____ UPIN/NPI: _____
Address: _____ City, State: _____ Zip: _____
Phone #: _____ Email Address: _____

Diagnosis: _____ Study Date: 5/3/2016 AHI: 5.9 Estimated length of need: _____ mths (99 = lifetime)

☐327.23 Obstructive Sleep Apnea (Adult & child) ☐327.21 Primary Central Sleep Apnea (includes Complex Sleep Apnea)
☐786.04 Cheyne-Stokes Breathing Pattern ☐Other: _____

[redacted]

☐ AutoSet™ or Easy-Breathe

- ☐ Use Cadco Default Settings
  Mode: Auto
  Max Press: 20 cm H_2O
  Min Press: 4 cm H_2O
  EPR™: OFF
- ☐ Mode: Auto (specify settings)
  Min Press: ____ cm H_2O (4 cm H_2O)
  Max Press: ____ cm H_2O (20 cm H_2O)
  Settling Time: ____ min(s) (OFF-45 min)
  EPR™: 1 2 3 (circle one)

Mirage Nasal Masks
- ☐ Mirage™ Micro
- ☐ Mirage SoftGel™

Swift Nasal Pillows
- ☐ Swift™

Mirage Full Face Masks
- ☐ Mirage Quattro™

Other
- ☐ ResMed Mask: _____

[redacted]

Compliance Reporting & Efficacy Data
- ☐ 30-Day download
- ☐ After ____ days, download data
- ☐ After ___ days, for ___ month(s)

- ☐ Heated
- ☐ Climate Line Tubing (available with S8)

*Do not substitute

Statement of Medical Necessity:
The above patient has undergone diagnostic evaluation. This evaluation has confirmed a positive diagnosis of sleep apnea. Positive airway pressure therapy is medically necessary and provides effective treatment of this disorder.

_____ _____
Physician Signature Date

3

John T Mather Memorial Hospital
Sleep Disorders Center
75 North Country Road
Port Jefferson, New York 11777
Phone (631) 476-2721 Fax (631) 476-2772

2

Patient Name: [redacted]

Date of Polysomnogram: 1/4/2016

Indication: Polysomnogram for diagnosis of sleep disorder.

Ordering Physician: Peter Ottavio D.O.

Referring Physician: [redacted]

This study was performed using the SomnoStar Pro sleep monitoring system. The following parameters were monitored: EEG via F3M2, F4M1, C3M2, C4M1, O1M2, O2M1, left and right outer canthus, submental electromylogram, 3 lead ECG, left and right anterior tibialis electromylogram, body position, respiratory effort utilizing Respitrace via Respiratory Inductance Plethysmography (RIP), snoring, saturation via pulse oximetry, airflow via thermal couple and pressure transducer. Hypopneas scored using AASM rule 1B. Study was performed on sleep system 8.

SOCIAL HISTORY:
This is a [redacted] who presents with complaints of frequent nocturnal awakenings, loud snoring, and excessive daytime sleepiness with an Epworth score of 8 out of 24. He is [redacted] inches tall and weighs [redacted] pounds for a BMI of [redacted]

MEDICATIONS:
Include: None listed.

Sleep Scoring Data:
Routine polysomnogram for diagnoses of sleep disorder was performed. The study began at 22:13 and was ended at 06:25. Patient slept for 93.5 minutes out of 493 minutes in bed representing a severely reduced sleep efficiency of 19.%. Sleep architecture showed a severely prolonged sleep latency of 44.5 minutes and a reduced stage R sleep latency of 0 minutes with a total of 0% stage R sleep being noted. Wake after sleep onset was 251.5 minutes. The patient was in stage N1 for 4 minutes, stage N2 for 87.5 minutes and stage N3 for 2 minutes. The patient was in stage N1 for 4.3% of TST, stage N2 for 93.6% of TST, and was in stage N3 for 2% of TST which severely reduced amount of slow wave sleep. There was a severely reduced amount of REM sleep with 0% REM sleep being noted.

Arousal Data
The patient had 109 arousals for an average of 69.9 arousals per hour of sleep.

Respiratory Events
Sleep disordered breathing was monitored and revealed 4 apneas. The apneas consisted of 1obstructive, 3central, and 0 mixed apneas. The apnea index was 2.6 apneas per hour of sleep. There were 57 hypopneas noted for an index of 36.6 hypopneas per hour of sleep. The overall apnea/hypopnea index

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Port Jefferson, New York 11777
Phone (631) 476-2721 Fax (631) 476-2772

Patient Name: [redacted]

Date of Polysomnogram: 1/4/2016

was 39.1 events per hour of sleep. There were 7 respiratory events (RERA's) with less than a 4% desaturation noted during the night and the overall respiratory disturbance index (AHI plus RERA's) was 43.6 events per hour of sleep. There was no evidence of hypoventilation. There was no evidence of Cheyne Stokes breathing.

Oxygen Saturation Statistics
The patient spent 92% of the evening with saturations greater than 89%. The lowest saturation noted was 88%. The lowest saturation during Non-REM was 88% with a mean of 91%. The lowest saturation during REM was 0% with a mean during REM of 0%.

Body Position Statistics
The patient slept 0% of the evening supine, 57% on his left side, 0% on his right side, and 43% in the prone position. The patient's AHI while supine was 0 events per hour of sleep and was 39 while non-supine.

Cardiac Events
EKG was monitored throughout the night and showed sinus rhythm. There were 0 PVC's noted and 0 PAC's noted during the night. Average heart rate while awake was 80 and average heart rate asleep was 72.

Movement Events
Limb movements were monitored throughout the night. There were 23 limb movement's noted for overall index of 14.8 PLMs per hour of sleep. There were a total of 11 limb movement's that were associated with arousals for an index of 7.1 per hour of sleep.

SUMMARY:

	TOTAL	INDEX
AHI	61	39.1
RDI	68	43.6
Arousals	109	69.9
PLMs	23	14.8
Lowest saturation	88%	
Mean saturation	93	

(* All values are during sleep)

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Phone (631) 476-2721 Fax (631) 476-2772

Patient Name: [redacted]

Date of Polysomnogram: 1/4/2016

CONCLUSION:
The patient has evidence of severe obstructive sleep apnea (ICD-9 780.53), snoring, periodic limb movemets, desaturations, and fragmentation of sleep.

RECOMMENDATIONS:
1. Treatment options include CPAP therapy, oral surgery, oral appliances, weight loss, and exercise.
2. Positional therapy and behavioral modification can also be recommended.
3. The patient is advised to return for CPAP titration.
4. The patient should return to discuss the results of the test as well as treatment options.
5. The patient should avoid alcohol, benzodiazepine, and benzodiazepine type medications, which could make the patient's sleep disordered breathing worse.
6. The patient is advised not to drive if drowsy or tired.

1/22/16

Peter Ottavio D.O., F.C.C.P.
Diplomate in Sleep Medicine A.B.I.M.

ResMed

ApneaLink - Report of 11/2/2015 5:29 PM

Treating physician

Referral to

Patient data

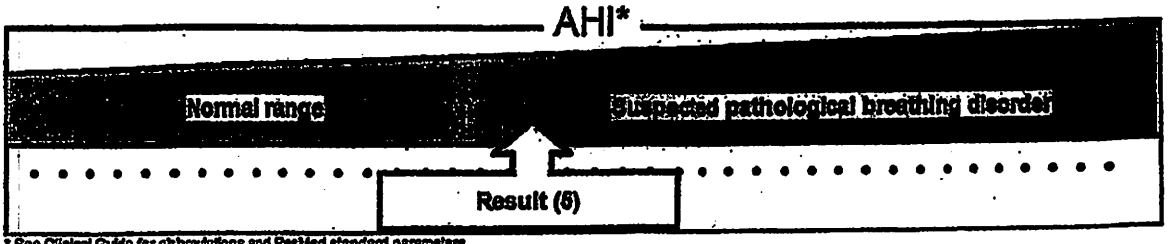
First name:	[redacted]	Patient ID:	
Last Name:		DOB:	[redacted]
Street:		Height:	0 ft 0 in
City, ST, Zip:		Weight:	0.00 lbs
Phone:		BMI:	kg/m²

Recording

Date:	10/28/2015
Start:	10:21 PM .
End:	5:03 AM .
Duration:	6 h 42 min

Evaluation

Start:	10:31 PM .
End:	5:01 AM .
Duration:	6 h 30 min



* See Clinical Guide for abbreviations and ResMed standard parameters

Analysis (Flow evaluation period: 6 h 30 min / SpO2 evaluation period: 6 h 31 min)

Indices		Normal	Result	
AHI*:	5.2	< 5 / h	Average breaths per minute [bpm]:	12.67
RI*:	10.4	< 5	Breaths:	4938
Apnea Index:	0.5	< 5 / h	Apneas:	3
UAI:	0		Unclassified apneas:	0 (0%)
OAI:	0.3		Obstructive apneas:	2 (67%)
CAI:	0.2		Central apneas:	1 (33%)
MAI:	0		Mixed apneas:	0 (0%)
Hypopnea Index:	4.8	< 5 / h	Hypopneas:	31
% Flow lim. Br. without Sn (FL):	40	< Approx. 60	Flow lim. Br. without Sn (FL):	1976
% Flow lim. Br. with Sn (FS):	16	< Approx. 40	Flow lim. Br. with Sn (FS):	814
			Snoring events:	2013
ODI Oxygen Desaturation Index*:	7.1	< 5 / h	No. of desaturations:	46
Average saturation:	93	94% - 98%	Saturation <= 90% :	6 min (2%)
Lowest desaturation:	87	-	Saturation <= 85% :	0 min (0%)
Lowest saturation:	87	90% - 88%	Saturation <= 80% :	0 min (0%)
Baseline Saturation:	95	%	Saturation <= 89% :	4 min (1%)
			Saturation <= 88% :	1 min (0%)
Minimum pulse:	54	> 40 bpm		
Maximum pulse:	103	< 80 bpm		
Average pulse:	68	bpm		
Proportion of probable CS epochs:	0	0%		

Analysis status: Analyzed automatically

Analysis parameters used (Default)

Apnea [20%; 10s; 60s; 1.0s; 20%; 60%; 6%]; Hypopnea [70%; 10s; 100s; 1.0s]; Snoring [8.0%; 0.3s; 3.6s; 0.5s]; Desaturation [4.0%]; CSR [0.50]

Comments

Firmware version:	SX586-0302
Software version	10.10
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